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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,540	12/11/2001	Nicholas Ling	690068.405C3	4186

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/14

Office Action Summary**Application No.**

10/015,540

Applicant(s)

LING ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-34, 73, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. Claims 30-34,73,74 are pending.
2. Rejections not reiterated from previous Office actions are hereby withdrawn.
The following rejections constitute the complete set presently being applied to the instant application

Claim Rejections - 35 USC § 112, second paragraph.

3. Claims 30-34 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims as amended read on the peptides which are up to 20 residues long and contain up to seven residues from a 14-mere fragment of myelin basic protein. That means that the peptide analogue as claimed contains residues other than residues of MBP. At the same time the claims require that N- and/or C- terminal residues are altered. It would be clear if these terminal residues belonged to natural MBP sequence; however, as they can be any residues, it is not clear compared to what they are being altered.

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Claim Rejections - 35 USC § 103.

4. Claims 31,32,34 are rejected under 35 U.S.C. § 103 as obvious over Wucherpfenig et al. in view of Nishimoto et al.

Wucherpfenig teaches peptide analogs comprising residues of 84-102 fragment of MBP with Ala or Arg substitutions of Lys 93 (Tables 4,5) which read on instantly claimed peptides wherein Lys-91 is substituted with Ala or Arg. The difference of the instantly claimed analogues is that their that N- and/or C- terminal residues are altered to reduce proteolysis. As the referenced analogs can be used in T cell recognition assays (Tables 4,5) and clinical trials that would demonstrate benefits from deletion/tolerization of MBP-specific cells (see end of p. 288), an artisan would be motivated to use stable MBP peptide analogues. Nishimoto teaches that the replacement of an L-amino acid residue with the corresponding D- isomer is a standard way of rendering the polypeptide less sensitive to proteolysis. See col. 15, line 2. It would have been obvious to an artisan at the time the invention was made to alter the terminal amino acid residues of MBP peptide analogs from L- to D-isomers to reduce proteolysis and thus to increase stability of the analogs.

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Double Patenting

5. Claims 30-34, 73, 74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,7 of U.S. Patent No. U.S. Patent No. 6,329,499. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,329,499. are drawn to peptides with substituted Lys-91, and, optionally N- or C-terminal residues (claim 7) or other residues (claims 1,2).

Applicant argues that the instant claims are amended to peptides that comprise no more than 20 amino acid residues. The same length peptide analogues, however, is the preferred embodiment of the referenced patent. See col. 5, lines 23, 24.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

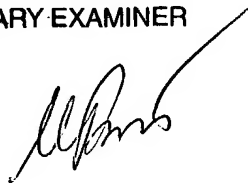
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

May 12, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.